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10/663,562	09/16/2003	Nina Rautonen	17031	2985

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EXAMINER	
BLAND, LAYLA D	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,16-20,24,26-28,30,32-35 and 37-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,16-20,24,26-28,30,32-35 and 37-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment submitted August 13, 2009, wherein claim 1 is amended, claims 2-4, 14-15, 23-23, 25, 29, 31, and 36 are canceled, and claims 37-44 are newly submitted. Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, and 37-44 are pending and are examined on the merits herein.

In view of the cancellation of claims 14 and 36, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted August 13, 2009, the objection to the disclosure for referring to Figures which are not present is withdrawn.

In view of Applicant's amendment submitted August 13, 2009, the rejection of claims 1, 5-14, 16-20, 26-28, 30, and 32-36 under 35 U.S.C. 102(b) as being anticipated by Olinger is withdrawn. Olinger does not teach administration to subjects suffering from a disease or disorder caused by accumulation of lactic acid.

In view of Applicant's amendment submitted August 13, 2009, the rejection of claims 1, 5-13, 19, 27, 28, 35, and 36 under 35 U.S.C. 102(b) as being anticipated by Jie is withdrawn because Jie does not teach administration of a polyol in combination with polydextrose. The rejection of claims 20 and 24 under 35 U.S.C. 103(a) as being unpatentable over Jie is withdrawn for the same reason.

In view of Applicant's amendment submitted August 13, 2009, the rejection of claims 1, 5-14, 16-19, 27, 28, 30, and 32-36 under 35 U.S.C. 102(b) as being anticipated by Takemori is withdrawn. Takemori does not teach administration to subjects suffering from a disease or disorder caused by accumulation of lactic acid.

In view of Applicant's amendment submitted August 13, 2009, the rejection of claims 1, 5-13, 16, 17, 19, 24, 26-28, 30, and 32-36 under 35 U.S.C. 102(e) as being anticipated by Shaw Craig is withdrawn. Shaw Craig does not teach administration to subjects suffering from a disease or disorder caused by accumulation of lactic acid.

In view of Applicant's amendment submitted August 13, 2009, the rejection of claims 1, 5-13, 19, 27, 28, 35, and 36 under 35 U.S.C. 102(b) as being anticipated by Solomons is withdrawn because Solomons does not teach administration of a polyol in combination with polydextrose. The rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Solomons in view of Borden is withdrawn for the same reason.

The following new or modified rejections were necessitated by Applicant's amendment submitted August 13, 2009, wherein claim 1 was amended to change the patient population to a "subject suffering from a disease or disorder caused by accumulation of lactic acid in the colon," and wherein new claims drawn to administration to patients suffering from acidosis, osteoporosis, or diarrhea, or administration of polydextrose and polyol to the patients recited in claim 38 are added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-13, 16-20, 24, 26-28, 30, 32-35, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include reduction to practice, level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that

distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Claim 1 and dependent claims 5-13, 16-20, 24, 26-28, 30, 32-35, and 42 recite the limitation "subject suffering from a disease or disorder caused by accumulation of lactic acid in the colon." Treatment of these diseases or disorders, or administration to subjects suffering from them, are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No treatment of any disease or disorder is reduced to practice. Although the specification, page 9, gives some examples of disorders caused by imbalanced fermentation, the correlation between imbalanced fermentation and the listed disorders is unclear based on knowledge in the art. For example, celiac disease, listed on page 9, is not known to be caused by imbalanced fermentation. Merck Manual Home Edition teaches that celiac disease is a hereditary condition characterized by intolerance to gluten and inflammation of the lining of the small intestine. The instant specification states that imbalanced fermentation leads to lactic acid accumulation in the large intestine, and the relationship of that condition to celiac disease is not clear. Thus, the scope of the claim is much larger than the scope of the description, and the skilled artisan could not extrapolate treatment of the list of disorders on page 9 to the treatment of other undisclosed disorders "caused by accumulation of lactic acid in the colon."

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the full scope of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 5-13, 16-20, 24, 26-28, 30, 32-35, and 42 recite the limitation "subject suffering from a disease or disorder caused by accumulation of lactic acid in the colon." It is unclear which diseases or disorders are caused by accumulation of lactic acid in the colon, and thus which subjects are being treated. The specification, page 9, states that acidosis, inflammation, allergy, celiac disease, osteoporosis and diarrhea can be caused by imbalanced fermentation in the colon, but

the list of conditions is not limiting. Thus, it is impossible to determine the metes and bounds of the claim.

Claim 30 depends from claim 14, which is canceled. For the purposes of examination, claim 30 will be treated as if it depends from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-13, 16-20, 24, 27, 28, 30, 32-35, and 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takemori et al. (US 5,711,982, January 27,

1998, of record) in view of Swagerty et al. (American Family Physician, Volume 65, Number 9, May 1, 2002, pages 1845-1850).

Takemori teaches de-lactose milk and milk powder products containing a sugar alcohol which can be lactitol and a bulking agent which can be polydextrose [column 3, lines 27-39]. The de-lactose milk or milk powder can be used in place of skim milk, whole milk powder and processed milk [column 4, lines 19-23]. An exemplary product contained 20.5 parts polydextrose and 14 parts lactitol [column 9, lines 39-47]. The chocolate was administered to a panel of high school students [column 10, lines 26-45]. Takemori is silent regarding purified polydextrose, but it is considered that the polydextrose was likely purified because it was administered to children.

Takemori does not teach administration to patients having particular diseases or disorders.

Swagerty teaches that persons with lactose intolerance experience abdominal pain and bloating, excessive flatus, and watery stool (diarrhea) following the ingestion of foods containing lactose [see abstract]. Patients should consider drinking lactose-reduced milk [page 1849, first paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer Takemori's de-lactose milk products to a patient suffering from lactose intolerance and the corresponding symptoms, because Takemori's milk products contain little or no lactose and lactose intolerant patients are advised to consume lactose-reduced products. It is known in the art that ingestion of

lactose causes symptoms in lactose intolerant patients, so the patients would be motivated to consume lactose-free products in order to avoid worsening of symptoms.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takemori et al. (US 5,711,982, January 27, 1998, of record) in view of Swagerty et al. (American Family Physician, Volume 65, Number 9, May 1, 2002, pages 1845-1850) and Borden et al. (US 5,601,863, February 11, 1997, of record).

Takemori teaches as set forth above, but does not teach the use of hydrogenated polydextrose.

Borden teaches that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydrogenated polydextrose for polydextrose in the above described method. Hydrogenated polydextrose is known as a functional equivalent of polydextrose, having improved properties such as color and flavor. Thus, the skilled artisan would expect an improvement in color and flavor using hydrogenated polydextrose.

The following rejections are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592, PTO-1449 submitted January 10, 2008).

Solomons teaches a study in which healthy adults of ages 19-45 years were administered 360 ml of intact milk or hydrolyzed milk containing 18 grams of polydextrose [page 586, Methods]. It is noted that no definition of "aged mammal" has been provided. A 45 year old human is in the second half of his or her lifespan, considering an average human lifespan of about 75-80 years, so he or she could reasonably be considered aged and the claims are anticipated.

Response to Arguments

Applicant argues that Solomons is not anticipatory because it does not disclose administering a food product comprising both a polyol and polydextrose. This argument is not persuasive because claims 38, 40, and 41 require only administration of polydextrose, not polyol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie teaches a study in which 4-12 grams of polydextrose per day were consumed by volunteers in order to study the physiologic effects. The polydextrose used was Litesse, provided by Danisco Cultor [page 1504, first paragraph], which is purified. Fecal pH decreased proportionally to polydextrose intake. Short-chain fatty acid production, notably butyrate, isobutyrate, and acetate, increased with polydextrose ingestion. *Bacteroides* (infection-causing bacteria) species decreased and *Lactobacillus* and *Bifidobacterium* (lactic acid bacteria) species increased. [page 1503,

Results] Jie also teaches that polydextrose is partially fermented in the large intestine and fermentation of polydextrose leads to diminished putrefactive microflora and suppressed production of carcinogenic metabolites [page 1503, column 2, lines 13-19]. A high fecal output and low bowel pH can suppress the production of enteric toxins, which plays an important role in the prevention of diverticulosis and reduces the risk of bowel cancer [page 1506, column 2, lines 16-18].

Jie et al. do not teach the administration of polydextrose to the subjects recited in claim 20 and do not teach incorporation of polydextrose into a sour milk product.

It would have been obvious to one of ordinary skill in the art to administer polydextrose in a food product to a subject having conditions associated with digestive and bowel health. Jie et al. teach that consumption of polydextrose improved bowel function, softened the feces, improved the ease of defecation, promoted the proliferation of favorable intestinal microflora and decreased the pH of the bowel [page 1508, last paragraph]. The skilled artisan could easily conceive of administering a compound that is useful for digestive and bowel health into a food composition. Thus, it would have been obvious to administer a composition that is useful for digestive and bowel health to subjects having conditions associated with digestive and bowel health, such as celiac disease and food allergy, or other conditions which affect digestive and bowel health.

Response to Arguments

Applicant argues that Jie does not teach administration of a food product comprising both a polyol and polydextrose. This argument is not persuasive because claims 38, 40, and 41 require only administration of polydextrose, not polyol.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, and 37-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-58 of copending Application No. 10/341,748. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each are drawn to administration of polydextrose and/or a polyol including lactitol. The instant claims are drawn to administration to a subject suffering from disorders caused by lactic acid in the colon or the patient population of claim 38, subjects at risk for imbalanced colon fermentation, including mammals treated with antibiotics and young mammals. The claims of copending Application No. 10/341,748

are drawn to treatment of a mammal or a mammal which has had antibiotic treatment or a young mammal at the age of weaning. Thus, the patient population in the instant claims has significant overlap with the patient population in copending Application No. 10/341,748 and the instant claims are obvious over the claims of copending Application No. 10/341,748.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623